



DEPARTMENT OF HEALTH AND HUMAN SERVICES

5 3195 d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 10, 2002

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-41

Paul J. Tourangeau, Owner
Koike Seafood, Inc.
500 South River Street
Seattle, Washington 98108

WARNING LETTER

Dear Mr. Tourangeau:

We inspected your firm located at 500 South River Street on 12/7/01, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you, some of which were previously brought to your attention, cause your tuna to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations regarding your Histamine/Scombroid - Toxin Forming Species HACCP plan were as follows:

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations at the Receiving and Refrigerated Storage critical control points to control for the histamine/scombroid toxin hazard listed in your HACCP plan.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for histamine producing fish lists a temperature critical limit at the receiving critical control point that is not adequate to control histamine. Your critical limit at the time of receiving is a "temperature no greater than 40°F at the time of receiving." The FDA has determined that the internal temperature of histamine producing fish at time of receipt is not a reliable critical limit unless the total transit time is 4 hours or less.

Paul J. Tourangeau, Owner
Koike Seafood, Inc., Seattle, WA
Re: Warning Letter SEA 02-41
Page 2

The FDA Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, recommends that all histamine producing fish delivered refrigerated (not frozen) to a secondary processor:

- a) Be accompanied by transportation records that show either the internal temperature of the product or the temperature of the conveyance throughout transportation; or
 - b) For fish delivered with total transit time of 4 hours or less, the internal temperature (not more than 40°F) of a representative number of fish in the lot at the time of delivery; or
 - c) For fish held under ice or chemical cooling media, the adequacy of ice or chemical cooling media at time of delivery.
3. You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for histamine producing fish lists a monitoring procedure at the receiving critical control point that is not adequate to control histamine. The FDA recommends either:
- a) That the firm continuously monitors the air temperature of the refrigeration equipment with a temperature recording device and check it at least twice daily.
 - b) That the firm monitors the histamine producing species by storing it completely covered in ice and check for adequacy of ice at least twice daily.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations. We may take further action if you do not promptly correct these violations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Paul J. Tourangeau, Owner
Koike Seafood, Inc., Seattle, WA
Re: Warning Letter SEA 02-41
Page 3

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand,
Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions
regarding any issue in this letter, please contact me at 425-483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement